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| 10/767,133 | 01/28/2004 | Martin W. Brechbiel | 225958 | 4301 |

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EXAMINER

JONES, DAMERON L

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,133

Applicant(s)

BRECHBIEL ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/28/04 & 9/27/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,10-15,21 and 22 is/are allowed.
- 6) ☒ Claim(s) 1,3-9,16,18,19,23-32 and 36-44 is/are rejected.
- 7) ☒ Claim(s) 17,20 and 33-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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APPLICANT'S INVENTION

1. Applicant's invention is directed to bifunctional compounds, methods of making the compounds, and uses thereof as set forth in independent claims 1, 2, 10, 12, 14, 19, 21, and 22.

Note: Claims 1-44 are pending.

DOUBLE PATENTING REJECTION

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 1, 3-9, 18, 23-25, 31, 32, and 36-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,696,551. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds encompassed by Formula (II) wherein R is CO₂H or CONHR'. A skilled practitioner in the art would recognize that the instant invention encompasses the patented invention since Formula II (instant invention) includes the R, R', n, and X values disclosed in the patented invention.

112 FIRST PARAGRAPH REJECTION

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16 and 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer and tumors, does not reasonably provide enablement for treatment of all diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC

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1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method of treating disease comprising administering a bifunctional compound.

(2) State of the prior art

The references do not indicate which specific diseases or class of diseases are treatable with the claimed compounds.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Claims 16, and 26-30 encompass a vast number of possible diseases. Applicant's specification does not enable the public to treat such a vast number of possible disease, but does specify that cancer and tumors may be treated with the compounds.

(4) Level of predictability in the art

The art pertaining to the treatment of disease using the compounds of the instant invention is highly unpredictable. Determining the various types of diseases or class of diseases that are treatable with the compounds of the instant invention requires various experimental procedures and without guidance that is applicable to diseased tissue, there would be little predictability in performing the claimed invention.

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(5) Amount of direction and guidance provided by the inventor

Claims 16 and 26-30 encompass a vast number of diseases. Applicant's limited guidance does not enable the public to treat such a numerous amount of disease using the compounds of the instant invention. There is no directional guidance for the diseases or specific diseased cells that are treatable with the instant invention. Hence, there is no enablement for all possible permutations and combinations diseased tissues treatable with the instant invention.

(6) Existence of working examples

Claims 16 and 26-30 encompass a vast number of disease. Applicant's limited working examples do not enable the public to treat such a numerous amount of diseases. While Applicant's claims encompass a plethora of possible diseases, the specification provides for various cancers and tumors only.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible diseases known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the

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state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTION

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 16, 19, and 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 26-30: The claims as written are ambiguous because it is unclear what disease Applicant is treating. Applicant is respectfully requested to clarify the claims in order that one may readily ascertain what is being claimed.

Claim 19: Did Applicant intend to write '²²⁵Ac' instead of '²⁵Ac'?

ALLOWABLE CLAIMS

8. Claims 2, 10-15, 21, and 22 are allowable over the prior art of record.

CLAIM OBJECTIONS

9. Claims 17, 20, and 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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COMMENTS/NOTES

10. The full scope of the instant invention has been searched. Thus, the restriction requirement is WITHDRAWN.


11. It should be noted that no prior art has been cited against Applicant's claims. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compounds, methods of making those compounds, and uses thereof having the formulae as set forth in independent claims 1, 2, 10, 12, 14, 19, 21, and 22.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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December 27, 2004